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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,210	07/28/2003	Daniel G. Brady	27556	5311

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EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 08/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/629,210	BRADY ET AL.	
	Examiner	Art Unit	
	Paul B. Prebilic	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 11-14, 33-37 and 40-44 is/are pending in the application.
- 4a) Of the above claim(s) 43 and 44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 11-14, 33-37 and 40-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/15/06</u> . | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

Newly submitted claims 43 and 44 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 43 and 44 are drawn to a method of use that requires separate placement steps. The originally claimed invention did not require separate steps but only required a product with distinct lenses.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 43 and 44 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Objections

Claims 1 and 7 are objected to because of the following informalities:

With regard to claim 1, the language "separate" does not appear to be grammatically proper. Rather, "separately" would appear appropriate.

With regard to claim 7, "vaulted" as used appears to positively claim the structure in combination with the eye. Therefore, the Examiner suggests changing "vaulted" to ---adapted to be vaulted--- in order to overcome this objection.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 40 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 40, the language "meniscus-type" is indefinite in that the "type" modifier makes the claim scope indefinite; see MPEP 2173.05(b) E that is incorporated herein by reference.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 8, and 40-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Lang et al (US 6,231,603). Lang anticipates the claim language where the primary lens as claimed is IOL (110) of Lang, and the supplemental lens as claimed is lens (72); see Figure 5 and column 6, line 32 et seq. Note that the IOL lens can be diffractive and that this language is written as the alternative, thus clearly suggesting that an wholly refractive or diffractive lens can be used; see column 4, lines 24-34 and column 1, lines 50-62. Furthermore, since IOL lens is multifocal it has to have an optical power of either positive or negative.

With regard to claim 8 specifically, there is no special definition for operatively coupled. Since the lenses of Lang operate with light, they are considered to be operatively coupled to the extent required by the present claim language.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 7, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lang et al (US 6,231,603) alone.

With regard to claim 3, since Lang teaches that the IOL lens (110 or 10) can be made of either hard or resilient materials (see column 4, lines 24-34), it would have been *prima facie* obvious to make the other lens (72) of resilient or hard material.

With regard to claim 7, Lang does not specifically teach making the lens (72) diffractive. However, since Lang teaches making the other lens either refractive or diffractive, it is the Examiner's position that it would have been considered clearly obvious to an ordinary artisan to do the same to the other lens for the same reasons as in the IOL (110).

With regard to claim 13, Lang does not specifically teach making the lens (72) multifocal. However, since Lang teaches that the IOL or primary lens can be multifocal, it is the Examiner's position that it would have been considered *prima facie* obvious to an ordinary artisan to make lens (72) multifocal as an alternative to or in addition to a multifocal IOL (110) lens.

Claims 33-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lang et al (US 6,231,603) in view of Cohen (US 5,117,306). Lang et al (US 6,231,603)

fails to describe the details of the diffractive lens embodiment, and thus, fails to disclose utilizing echelettes and the diffraction profile. However, Cohen teaches that it was known to make diffractive intraocular lenses that are positively or negatively powered, that include echelettes, and that have first or multi-ordered profiles as claimed; see the figures and claims 19 and 22 thereof. Therefore, it is the Examiner's position that it would have been obvious to provide a diffractive supplemental lens having the characteristics disclosed by Cohen for the same reasons Cohen uses the same and in order to make a wide variety of lenses suitable for many different patients.

Regarding claim 35, the echelettes of the formula of column 1, line 35 are on the order of a wavelength of light in size. For this reason, they would not be visible to the naked eye since they are so small.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lang et al (US 6,231,603) and Cohen (US 5,117,306) as applied to claims 33-39 above, in further view of Patel (US 5,366,502). Lang et al (US 6,231,603) fails to use a toric diffractive lens as claimed. However, Patel teaches that such lenses were known; see column 8, lines 1-10. Therefore, it is the Examiner's position that it would have been obvious to use a toric lens in the Lang invention for the same reasons that Patel uses the same and in order to aid a patient with an astigmatism (via a toric lens).

Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lang et al (US 6,231,603) in view of Portney (US 6,197,058) or Nordan et al (US 2003/0097176). Lang fails to teach the thickness of the diffractive supplemental lens as claimed. However, Portney (see column 7, lines 59-62) and Nordan (see abstract) both

teach that lens thicknesses of less than 250 microns were known. Therefore, it is the Examiner's position that it would have been *prima facie* obvious to make the Lang supplemental lens less than 250 microns thick for the same reasons as the secondary references, and in order to make the lens insertable through a small incision.

Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lang et al (US 6,231,603) in view of Copeland et al (US 2002/0042653). Lang fails to teach a blue blocker or tint feature as claimed. However, Copeland teaches that it was known to incorporate blue blocking or tint into intraocular lenses prior to the invention of the Applicants' invention; see the abstract. Therefore, it is the Examiner's position that it would have been *prima facie* obvious to incorporate blue blocker or tint into the lens of Lang for the same reasons that Copeland does the same, that is, to achieve maximum visual acuity.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lang et al (US 6,231,603) in view of Bandhauer et al (US 2004/0230300) or Miller (WO 03/000154). As an alternative interpretation of "operatively coupled" of claim 8 that requires a physical coupling of the two lenses, the Examiner sets forth the following rejection. Lang can be interpreted as not meeting the claim language because it could be said to not teach operatively coupling of the lenses in that they are not shown physically coupled. However, both Bandhauer and Miller teach that it was known to physically couple similar lens systems together; see Figure 11 of Bandhauer and see Figure 6 of Miller. Therefore, it is the Examiner's position that it would have been *prima facie* obvious to couple the lenses of Lang together at the extreme ends thereof for the

same reasons that the secondary references do the same or to set the distance from each other prior to accommodation.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending

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claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Paul Prebilic
Primary Examiner
Art Unit 3738